EXHIBIT VI

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¹ Deceased, April 1967.

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EXHIBIT VIII

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ALBANY, N.Y.	Northeastern New York, and portions of	Frank M. Woolsey, Jr., M.D. Associate Dean			San Francisco, California 94102
	Southern Vermont and Western Massachusetts.	Albany Medical College of Union University 47 New Scotland Avenue Albany, New York 12208	CENTRAL NEW YORK.	Syracuse, New York, and 15 surrounding counties.	Richard H. Lyons, M.D. Professor and Chairman Department of Medicine State University of New York
ARIZONA.	Arizona.	Merlin K. DuVal, M.D. Acting Dean University of Arizona			Upstate Medical Center 766 Irving Avenue Syracuse, New York 13210
		College of Medicine Tucson, Arizona 85721	COLORADO- WYOMING.	Colorado and Wyoming.	C. Wesley Eisele, M.D. Associate Dean for Postgraduate
ARKANSAS.	Arkansas.	Winston K. Shorey, M.D. Dean, University of Arkansas School of Medicine 4301 West Markham Street Little Rock, Arkansas 72201	WTOMING.		Medical Education University of Colorado Medical Center 4200 East Ninth Avenue Denver, Colorado 80220
BI-STATE.	Eastern Missouri and Southern Illinois centered around St. Louis.	William H. Danforth, M.D. Vice Chancellor for Medical Affairs Washington University 660 South Euclid Avenue St. Louis, Missouri 63110	CONNECTICUT.	Connecticut.	Henry T. Clark, Jr., M.D. Program Coordinator Connecticut Regional Medical Program 272 George Street New Haven Connecticut 06510

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GEORGIA.	Georgia.	J. W. Chambers, M.D. Medical Association of Georgia 938 Peachtree Street N.E.			1100 West Michigan Street Indianapolis, Indiana 46207
		Atlanta, Georgia 30309	INTERMOUNTAIN.	Utah and portions of	C. Hilmon Castle, M.D.
GREATER DELAWARE VALLEY.	Eastern Pennsylvania and portions of Delaware and New Jersey.	William C. Spring, Jr., M.D. Greater Delaware Valley Regional Medical Program 301 City Line Avenue Bala-Cynwyd,		Colorado, Idaho, Montana, Nevada, and Wyoming.	Associate Dean and Chairman Department of Postgraduate Education University of Utah Salt Lake City, Utah 84112
		Pennsylvania 19004	IOWA.	Iowa.	Willard Krehl, M.D., Ph. D.
HAWAII.	Hawaii.	Windsor C. Cutting, M.D. School of Medicine University of Hawaii 2538 The Mall Honolulu, Hawaii 96822			Director, Clinical Research Center Department of Internal Medicine University Hospital University of Iowa Iowa City, Iowa 52240
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MAINE.	Maine.	Manu Chatterjee, M.D. Merrymeeting Medical Group Brunswick, Maine	MISSISSIPPI.	Mississippi.	Guy D. Campbell, M.D. University of Mississippi Medical Center 2500 North State Street Jackson, Mississippi 39216
MARYLAND.	Maryland.	Thomas B. Turner, M.D. Dean, The John Hopkins University School of Medicine 725 Wolfe Street Baltimore, Maryland 21205	MISSOURI.	Missouri.	Vernon E. Wilson, M.D. Dean, School of Medicine University of Missouri Columbia, Missouri 65201
MEMPHIS.	Western Tennessee, Northern Mississippi, and portions of Arkansas, Kentucky, and Missouri.	James W. Culbertson, M.D. Professor and Cardiologist Department of Internal Medicine University of Tennessee College of Medicine Memphis, Tennessee 38103	MOUNTAIN STATES.	Idaho, Montana, Nevada, and Wyoming.	Kevin P. Bunnell, Ed. D. Associate Director Western Interstate Commission for Higher Education University East Campus 30th Street Boulder, Colorado 80302
METROPOLITAN WASHINGTON, D.C.	District of Columbia and 2 contiguous counties in Maryland, 2 in Virginia and 2 independent cities in Virginia.	Thomas W. Mattingly, M.D. Program Coordinator District of Columbia Medical Society 2007 Eye Street N.W. Washington, D.C. 20006	NEBRASKA-SOUTH DAKOTA.	Nebraska and South Dakota.	Harold Morgan, M.D. Nebraska State Medical Association 1408 Sharp Building Lincoln, Nebraska 68508

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		Plaza Trenton, New Jersey 08625	NORTHLANDS.	Minnesota.	J. Minott Stickney, M.D. Minnesota State Medical Associ-
NEW MEXICO.	New Mexico.	Reginald H. Fitz, M.D. Dean, University of New Mexico School of Medicine Albuquerque, New Mexico 87106			ation 200 First Street, Southwest Rochester, Minnesota 55901
NEW YORK METRO- POLITAN AREA.	New York City, and Nassau, Suffolk, and Westchester Counties.	Vincent de Paul Larkin, M.D. New York Academy of Medicine 2 East 103d Street New York, New York 10029	OHIO STATE.	Central and Southern two-thirds of Ohio (61 counties, excluding Metropolitan Cincin- nati area).	Richard L. Meiling, M.D. Dean, Ohio State University College of Medicine 410 West 10th Avenue Columbus, Ohio 43210
NORTH CAROLINA.	North Carolina.	Marc J. Musser, M.D. Executive Director North Carolina Regional Medical Program Teer House 4019 North Roxboro Road Durham, North Carolina 27704	OHIO VALLEY.	Greater part of Kentucky and contiguous parts of Ohio, Indiana, and West Virginia.	William H. McBeath, M.D. Director, Ohio Valley Regional Medical Program 1718 Alexandria Drive Lexington, Kentucky 40504
NORTH DAKOTA.	North Dakota.	Theodore H. Harwood, M.D. Dean, School of Medicine University of North Dakota Grand Forks, North Dakota 58202	OKLAHOMA.	Oklahoma.	Kelly M. West, M.D. University of Oklahoma Medical Center 800 N.E. 13th Street Oklahoma City, Oklahoma 73104

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		Portland, Oregon 97201	TENNESSEE MID- SOUTH.	Eastern and Central Tennessee and contigu-	Stanley W. Olson, M.D. Professor of Medicine
ROCHESTER, NEW YORK.	Rochester, New York and 11 surrounding counties.	Ralph C. Parker, Jr., M.D. Clinical Associate Professor of Medicine University of Rochester School		ous parts of Southern Kentucky and North- ern Alabama.	Vanderbilt University Baker Building 110 21st Avenue, South Nashville, Tennessee 37203
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		ogy) Department of Medicine Medical College Hospital 55 Doughty Street Charleston, South Carolina 29403	TRI-STATE.	Massachusetts, New Hampshire and Rhode Island.	Norman Stearns, M.D. Medical Care and Educational Foundation 22 The Fenway Boston, Massachusetts 02115

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WASHINGTON- ALASKA.	Alaska and Washington.	Donal R. Sparkman, M.D. Associate Professor of Medicine University of Washington School of Medicine Seattle, Washington 98105	WESTERN PENNSYL- VANIA.	Pittsburgh, Pennsylvania and 28 surrounding counties.	Francis S. Cheever, M.D. Dean, School of Medicine University of Pittsburgh Flannery Building 3530 Forbers Avenue Pittsburgh, Pennsylvania 15213
WEST VIRGINIA.	West Virginia.	Charles L. Wilbar, M.D. West Virginia University Medical Center Morgantown, West Virginia 26506	WISCONSIN.	Wisconsin.	John S. Hirschboeck, M.D. Wisconsin Regional Medical Program, Inc. Room 1103 110 East Wisconsin Avenue Milwaukee, Wisconsin 53202

EXHIBIT IX

Review and Approval of Operational Grants

This exhibit outlines review and approval procedures for use in reviewing grants for the establishment and operation of Regional Medical Programs authorized by Section 904(a) of Title IX of the Public Health Service Act.

Background

These procedures were developed after extensive consideration of: (1) the philosophy and purposes of Title IX; (2) the initial experience in reviewing the planning grant applications awarded under Section 903; (3) consideration of the first operational grant proposals, including site visits to the regions involving members of the National Advisory Council on Regional Medical Programs and the Regional Medical Programs Review Committee; (4) preliminary discussion of the issues involved in the review of operational applications by the National Advisory Council on Regional Medical Programs at its November 1966 meeting; and (5) extensive discussion with both the Review Committee and the National Advisory Council concerning the effectiveness of these procedures during the actual review of the first operational applications. As a result of these considerations, the resulting review and approval process is to the greatest possible extent keyed to the anticipated nature of operational grant requests and to the policy issues inherent in the Regional Medical Programs concept.

Characteristics of Operational Grants

In designing this review process, attention has been given to the following characteristics of applications for Regional Medical Program grants: (1) complexity of the proposals with many discrete but interrelated activities involving different medical fields; (2) the diversity of grant proposals resulting from encouragement of initiative and determination at the regional level within the broad parameters provided in the Law, Regulations, and Guidelines: (3) the many different attributes of the overall operational proposals which need to be evaluated during the review process, including not only the merit of highly technical medical activities in the fields of heart disease, cancer, stroke, and related diseases but also the effect of the proposal on improved organization and delivery of health services and the degree of effective cooperation and commitment of the major medical resources: (4) the relationships of the proposals to the responsibilities of many other components of the Public Health Service and other Federal programs; (5) the characteristics of these initial proposals as the first steps in the more complete development of the Regional Medical Program, guided by a continuing planning process.

Objectives of Review Process

The objectives sought in the development of this review process are based on a careful assessment of the goals of the Regional Medical Programs and how the achievement of those goals can be most effectively furthered by the process used in making decisions on the award of grant funds. Consideration of these basic policy issues led to delineation of the following objectives of the review process:

☐ The operational grant application must be viewed as a totality rather than as a collection of discrete and separate projects.

The decision-making process for the review and approval of operational grants must be developed in a way that stimulates and preserves the essential goal setting, priority determination, decision making and evaluation at the regional level.

During the review process the staff of the Division of Regional Medical Programs and the review groups must be concerned with the probability of effective implementation of the proposed accivities in addition to the inherent technical merit of the specific proposals.

☐ The review process must provide the opportunity for the reviewers to assure a basic level of quality and feasibility of the individual activities that will make an investment of grant funds worthwhile.

☐ The review process must have sufficient flexibility to cope with the variety of operational proposals submitted, allowing for the tailoring of the review to the needs of the particular proposal.

The review process should enable the staff and reviewers to view a Regional Medical Program as a continuing activity, rather than a discrete project with time limits. Therefore, the review process should have continuity during the grant activity and should provide the opportunity to judge the development of Regional Medical Programs on the basis of results and evaluation of progress, in addition to the evaluation of the probable effectiveness of initial proposals.

Criteria

The basic criteria for the review of Regional Medical Program grant requests are set forth in the Regulations as follows:

"Upon recommendation of the National Advisory Council on Regional Medical Programs, and within the limits of available funds, the Surgeon General shall award a grant to those applicants whose approved programs will in his judgment best promote the purposes of Title IX. In awarding grants, the Surgeon General shall take into consideration, among other relevant factors the following:

- "(a) Generally, the extent to which the proposed program will carry out, through regional cooperation, the purposes of Title IX, within a geographic area.
- "(b) The capacity of the institutions or agencies within the program, individually and collectively, for research, training, and demonstration activities with respect to Title IX.
- "(c) The extent to which the applicant or the participants in the program plan to coordinate or have coordinated the Regional Medical Program with other activities supported pursuant to the authority contained

in the Public Health Service Act and other Acts of Congress including those relating to planning and use of facilities, personnel, equipment, and training of manpower.

- "(d) The population to be served by the Regional Medical Program and relationships to adjacent or other Regional Medical Programs.
- "(e) The extent to which all the health resources of the region have been taken into consideration in the planing and/or establishment of the Program.
- "(f) The extent to which the participating institutions will utilize existing resources and will continue to seek additional nonfederal resources for carrying out the objectives of the Regional Medical Program.
- "(g) The geographic distribution of grants throughout the Nation."

In utilizing these criteria in the review process, it was determined that the sequence of consideration of the various attributes of the proposal would be important if the objectives of the review process listed above were to be achieved. The review process, therefore, must focus on three general characteristics of the total proposal which separately and yet collectively determine its nature as a

comprehensive and potentially effective Regional Medical Program:

The first focus must be on those elements of the proposal which identify it as truly representing the concept of a regional medical program. The review groups have determined that it is not fruitful to consider specific aspects of the proposal unless this first essential determination concerning the core of the program is positive. In making this determination, considerations include such questions as: "Is there a unifying conceptual strategy which will be the basis for initial priorities of action, evaluation, and future decision making?" "Is there an administrative and coordinating mechanism involving the health resources of the regions which can make effective decisions, relate those decisions to regional needs, and stimulate the essential cooperative effort among the major health interests?" "Will the key leadership of the overall Regional Medical Program provide the necessary guidance and coordination for the development of the program?" "What is the relationship of the planning already undertaken and the ongoing planning process to the initial operational proposal!"

After having made a positive determination about this core activity, the next step widens the focus to in-

clude both the nature and the effectiveness of the proposed cooperative arrangements. In evaluating the effectiveness of these arrangements, attention is given to the degree of involvement and commitment of the major health resources, the role of the Regional Advisory Group, and the effectiveness of the proposed activities in strengthening cooperation. Only after the determination has been made that the proposal reflects a regional medical program concept and that it will stimulate and strengthen cooperative efforts will a more detailed evaluation of the specific operational activities be made.

☐ If both of the two previous evaluations are favorable, the operational activities can then be reviewed, individually and collectively. Each activity is judged for its own intrinsic merit, for its contribution to the cooperative arrangements, and for the degree to which it includes the core concept of the Regional Medical Programs. It should also fit as an integral part of the total operational activities, and contribute to the overall objectives of the Regional Medical Programs.

Review Procedures

Below is a chart which describes the various steps in the review process

which will be applied to initial operational grant proposals from each region. The first four operational grant proposals were subject to the various steps of this process. Those steps were not carried out in precisely the order and sequence provided in this chart since the first four applications were used as a test situation for the development of this operational procedure. It is also likely that further experience will lead to appropriate modification of these procedures. The following comments may help to explain this review process, which has been agreed to by the Regional Medical Programs Review Committee and the National Advisory Council on Regional Medical Programs. The complexity of these grant requests and the steps in the review process which seems appropriate for their review will require as much as 6 months for the completion of the total review process in most cases.

☐ Initial Consideration by Review Committee—The first steps of the review process involve preparation for the site visit which will be conducted for each operational grant application. The first consideration of the application by the Review Committee will be for the purposes of pro-

viding information and comments for the guidance of the site visit team, utilizing staff analyses of the planning grant experience, considerations of gross technical validity, policy issues raised by the particular application, and initial input on relationships to other Federal programs.

Site Visit—Initial experience has indicated that a site visit by members of the Review Committee and the National Advisory Council is essential for the assessment of the overall concept and strategy used by the Regional Medical Program in developing the operational proposal and for assigning priorities to specific projects included in the proposal. It also provides the opportunity to assess the probable effectiveness of cooperative arrangements and degree of commitment of the many elements which will be essential to the success of a Regional Medical Program. As the discussion above points out, favorable conclusions on these aspects of the Regional Medical Program must be reached before it is justifiable to begin the major investment of the time of the Division staff, technical reviewers in other parts of the Public Health Service, technical consultants, and the Division of Regional Medical Program review groups,

which is required for the assessment of the various components of the application. The site visit is not a substitute for the investment of this effort but provides the opportunity to evaluate the cooperative framework of the Regional Medical Program and the overall probability of the success of the proposed program.

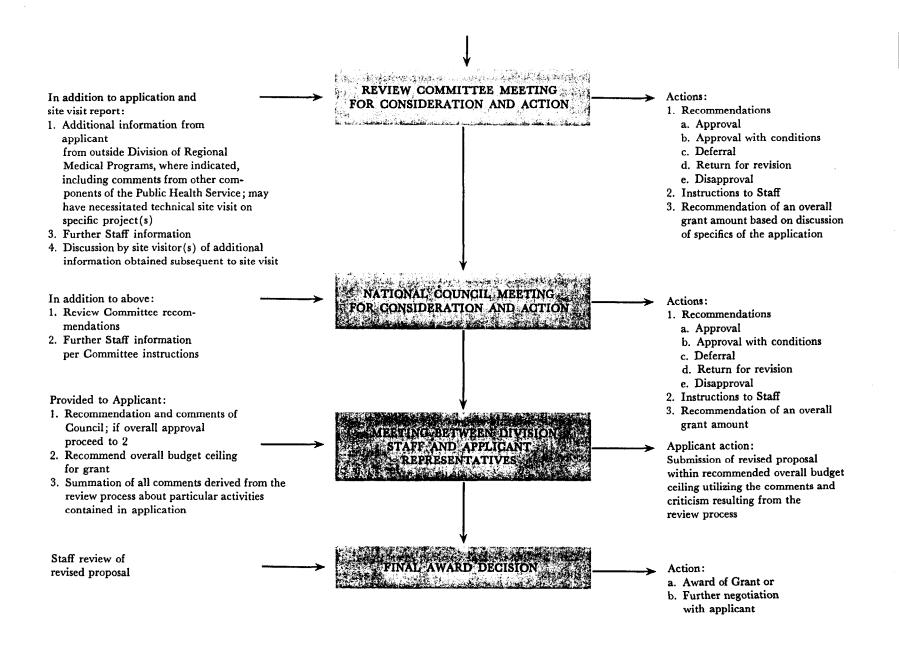
☐ Intensive Analysis and Technical Reviews-If the site visit report justifies the investment of additional effort in the review of the application, the Division staff proceeds with an intensive analysis of the specifics of the application. This analysis provides the framework for obtaining specific comments from other components of the Public Health Service and other Federal health agencies with related programs, detailed comments from the various components of the Division of Regional Medical Programs staff, technical site visits on specific projects within the overall application when considered necessary, and for the assimilation of additional information from the applicant as a result of the site visit. The technical review of specific projects should not only evaluate the intrinsic merit of the project but should help to identify specific problems on any project which might prevent that

project from making a meaningful contribution to the objectives of the Regional Medical Program. Technical reviews also consider the justification for the particular project budget as presented. This aspect of the review process presents the opportunity to consider possible overlaps and duplications with other Public Health Service programs which can be a factor in determining how much support should be provided for the particular activity from the Regional Medical Program grant. The opportunity to raise these questions is not limited to Division of Regional Medical Programs staff initiative since copies of all applications are distributed to the interested National Institutes of Health, to all Bureaus of the Public Health Service, and to the National Library of Medicine at the time of receipt. Representatives from all these organizations are invited to meetings of the Review Committee.

☐ Second Review by Review Committee and Recommendation for Action—The Review Committee considers all of the information available concerning the application. In addition to the application itself and the site visit report, a summary of all available information is presented to the Committee in a staff presenta-

Operational Grant Review and Approval Process REVIEW COMMITTEE MEETING Guidance for Site Visit Team FOR INFORMATION AND COMMEN Initial Staff Information re: a. Planning grant experience b. Gross technical validity c. Policy issues d. Relationship to other Federal programs SITE VISIT Judgments re: Review Committee Guidance 1. Concept of Regional Medical Programs 2. Cooperative Arrangements 3. Relationship of projects, one to another and to the 4. Approximate magnitude of support warranted (Prepared 2d day by site team) 5. Quality of projects where appropriate REPORT

Flow Chart
Operational Grant Review and Approval Proces



tion. The Review Committee then makes its recommendation concerning the application. Because of the complex nature of the applications, the Review Committee can divide its recommendation into several parts relating to different parts of the application. If there is an overall favorable recommendation on the readiness of the Regional Medical Program to begin the operational program, the Review Committee recommends an overall grant amount based on a discussion of the specifics of the application. This amount takes into consideration problems raised by technical reviewers, overlap with other programs, feasibility of the proposals, and other relevant considerations raised during the review process. While the overall amount recommended is based on discussion of the specific components of the total application, the recommendation does not in most cases include specific approval or disapproval of individual projects except when a project is judged to be infeasible, to be outside the scope of Regional Medical Programs, to be an undesirable duplication of ongoing efforts, or to lack essential technical soundness.

Review by National Advisory Council on Regional Medical Pro-

grams—The National Advisory Council considers the Review Committee recommendations. It has available to it the full array of material presented to the Review Committee and a staff summary of that material. Further information obtained by the staff on the instructions of the Review Committee may also be presented. The National Advisory Council makes the required legal recommendation concerning approval of the application, including recommendations on the amount of the grant. The Council may delegate to the staff the authority to negotiate the final grant amount within set limits. A recommendation of approval applies to all projects except when indicated by the Council, even though the grant amount recommended may be less than the amount requested because of the judgments applied during the review of the application or because of overall limitations of funds.

☐ Meeting with Representatives of the Applicant—Following the National Advisory Council meeting, the staff of the Division meets with representatives of the applicant and presents to them the recommendation and comments of the Council. If the recommendation is favorable and the Division intends to award a grant, the staff also presents the recommended overall budget ceiling for the grant along with a summation of all the comments derived from the review process concerning particular activities contained within the application, including criticisms of specific projects and comments about the budget levels proposed for specific projects. The staff also indicates if any projects included in the application are not to be included in a grant award because of Council recommendation or Division decision based on negative factors as discussed above.

Submission of Revised Proposal-On the basis of this meeting, the applicant submits a revised proposal within the recommended overall budget ceiling, utilizing in the revision the comments and criticisms and technical advice resulting from the review process. This step of the process requires the applicant to reconsider their priorities within the recommended budget level and to assume the basic responsibility for making the final decisions as to which activities will be included in the operational program. Unless a project has been specifically excluded from the approval action, the applicant may choose to undertake an activity even if doubts about the

activity were raised during the review process. The applicant includes such an activity with the understanding that the progress of the activity will be followed with special interest by the review groups and will be judged in the future on the basis of results.

Final Award Decision—Following staff review of the revised proposal, the final decision on the award is made by the Division Director. Additional negotiations with the applicant may also take place.

June 1967

EXHIBIT X

Principal Staff of the Division of Regional Medical Programs, June 30, 1967

The Office of the Director provides program leadership and direction.

Robert Q. Marston, M.D. Director

Karl D. Yordy

Assistant Director for Program Policy

William D. Mayer, M.D.

Associate Director for Continuing Education

Charles Hilsenroth

Executive Officer
Maurice E. Odoroff

Assistant to Director for Systems and Statistics

Edward M. Friedlander

Assistant to Director for Communications and Public Information

The Continuing Education and Training Branch provides assistance for the quality development of such activities in Regional Medical Programs.

William Mayer, M.D.
Chief
Cecilia Conrath
Assistant to Chief
Frank L. Husted, Ph. D.
Head, Evaluation Research Group

The Development and Assistance Branch serves as the focus for two-way communication between the Division and the individual Regional Medical Programs.

Margaret H. Sloan, M.D.

Chief
Ian Mitchell, M.D.

Associate for Regional Development

The Grants Management Branch interprets grants management policies and reviews budget requests and expenditure reports.

James Beattie
Chief

The Grants Review Branch handles the professional and scientific review of applications and progress reports.

Martha Phillips
Acting Chief

The Planning and Evaluation Branch appraises and reports on overall program goals, progress and trends and provided staff work for the Surgeon General's Report to the President and the Congress.

Stephen J. Ackerman
Chief
Daniel I. Zwick
Assistant Chief
Roland L. Peterson
Head, Planning Section
Rhoda Abrams
Acting Head, Evaluation Section

EXHIBIT XI

Complementary Relationships Between the Comprehensive Health Planning and Public Health Service Amendments of 1966 and the Heart Disease, Cancer, and Stroke Amendments of 1965

A Fact Sheet from the Office of the Surgeon General, Public Health Service, March, 1967

Public Law 89-749, the Comprehensive Health Planning and Public Health Services Amendments of 1966, establishes mechanisms for comprehensive areawide and State-wide health planning, training of planners, and evaluation and development efforts to improve the planning art. Public Law 89-239, the Heart Disease, Cancer, and Stroke Amendments of 1965, authorized grants to assist in the planning, establishment, and operation of regional medical programs to facilitate the wider availability of the latest advances in care of patients afflicted with heart disease, cancer, stroke, and related diseases. Public Law 89-239 has been in operation for about a year. Public Law 89-749 is yet to be implemented.

The purposes of P.L. 89-749, described in Section 2(b) are: to establish "comprehensive planning for health services, health manpower, and health facilities" essential "at every level of government"; to strengthen "the leadership and capacities of State health agencies"; and to broaden and make more flexible Federal "support of health services provided people in their communities."

P.L. 89-749 asserts that these objectives will be attained through "an effective partnership, involving close intergovernmental collaboration, official and voluntary efforts, and participation of individuals and organizations. . . " The Act establishes a new mechanism to relate varied planning and health programs to each other and to other efforts in achievement of a total health purpose.

The law has five major sections:

- Formula grants to the States for comprehensive health planning at the State level through a designated State agency;
- Grants for comprehensive health planning at the areawide level;
- Grants for training health planners;

Formula grants to States for public health services;

☐ Project grants for health services development

The purpose of P.L. 89-239, as set forth in Section 900(b) of the Public Health Service Act, is "To afford to the medical profession and the medical institutions of the Nation, through . . . cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of (heart disease, cancer, stroke, and related) diseases. . . ."

The process for achieving this purpose is to establish regional cooperative arrangements among science, education, and service resources for health care . . ." for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases. . . ." (Section (a))

This law focuses on the cooperative involvement of university medical centers, hospitals, practicing physicians, other health professions, and voluntary and official health agencies in seeking ways to build effective linkages between the development of new knowledge and its application to the problems of patients. The law provides flexible mechanisms which em-

phasize the exercise of initiative and responsibility at the regional level in identifying problems and opportunities in seeking these objectives and in developing specific action steps to overcome the problems and exploit the opportunities.

The Public Health Service sees P.L. 89-239 and P.L. 89-749 as serving the common goal of improved health care for the American people along with other Public Health Service and non-Public Health Service grant programs such as community mental health centers, migrant health programs, air pollution control, programs for the training of health manpower, the neighborhood health centers under the Office of Economic Opportunity, the medical programs of the Children's Bureau, and State and local health programs. In the States and communities, P.L. 89-749 will provide a vehicle for effective interaction among these programs, recognizing as it does that the diversity of the various States and areas of the Nation is considerable, and that the specific relationships between and among programs will have to be worked out at these levels rather than through a specific Federal mandate.

The planning resources created at the State and local level under Public Law 89-749 are expected to afford valuable assistance in the achieve-

ment of the objectives of Public Law 89-239, other programs of the Public Health Service, and other health endeavors in each of the States. Public Law 89-749 provides, however no authority for these planning resources to impose their conclusions or recommendations on any other programs, Federal or non-Federal, except for activities carried out under Section (d) and parts of Section (e) of the Law which must be in accordance with the comprehensive State health plan developed by the State comprehensive health planning agency. The Public Health Service intends to stimulate effective interaction among these programs, recognizing that the diversity of the various States and areas of the Nation is considerable.

Both P.L. 89-239 and P.L. 89-749 provide flexible instruments for establishing productive relationships between these and other programs. The maintenance of this flexibility in the administration of the grant programs will permit each State and region to design and develop a relationship that is appropriate for its particular circumstances. Both programs call for a close private-public partnership. Both programs must place dependence on imaginative, reasonable local approaches to cooperation and coordination. Both programs recognize that they can only achieve their full potential by the close and complete involvement of other components of the health endeavor. A vital partnership must be developed between the Federal government, the universities, local and State government, the voluntary health interests and individuals and organizations designed to develop creative action for health.

The Congress recognized the relationship of comprehensive health planning to other planning activities. The Report of the Senate Committee on Labor and Public Welfare (No. 1655, September 29, 1966) stated:

"The comprehensive planning of the State health planning agency with the advice of the council would complement and build on such specialized planning as that of the regional medical program and the Hill-Burton program, but would not replace them. . . ."

"The State health planning agency provides the mechanism through which individual specialized planning efforts can be coordinated and related to each other. The agency will also serve as the focal point within the State for relating comprehensive health plans to planning in areas outside the field of health, such as urban redevelopment, public housing, and so forth."

Characteristics of These Two Important Acts

The complementary relationship of the programs established by P.L. 89–239 and P.L. 89–749 to foster development of a "Partnership for Health" is illustrated by the following outline of some of their major elements.

Scope

P.L. 89–239: The Regional Medical Program. To identify regional needs and resources relating to heart disease, cancer, stroke, and related diseases and to develop a regional medical program which utilizes regional cooperative arrangements to apply and strengthen resources to meet the needs in making more widely available the latest advances in diagnosis and treatment of these diseases.

P.L. 89-749: The Comprehensive Health Planning Program. To establish a planning process to achieve comprehensive health planning on a Statewide basis which identifies health problems within the State, sets health objectives directed toward improving the availability of health services, identifies existing resources

and resource needs, relates the activities of other planning and health programs to the meeting of these health objectives, and provides assistance to State and local officials, private voluntary health organizations and institutions, and other programs supported by PHS grant funds in achieving the more effective allocation of resources in accomplishing the objectives.

Participants

P.L. 89–239: University medical centers, hospitals, practicing physicians, other health professions, voluntary and public health agencies, and members of the public. A regional advisory group representing these interests and playing an active role in the development of the regional program must approve any application for operational activities of the regional medical program.

P.L. 89-749: State agency designated by the Governor does the planning. State advisory council advises on the planning process. Membership must include more than half consumer representation. Membership will also include voluntary groups, practitioners, public agencies, general planning agencies, and universities.

The Process
P.L. 89–239:
Establish cooperative arrangements among science, education, and service resources.
Assess needs and resources.
Develop pilot and demonstration projects, emphasizing flow of knowledge in uplifting the cooperative capabilities for diagnosis and care of patients.
☐ Relate research, training, and service activities.
Develop effective continuing education programs in relation to other operational activities.
Develop mechanisms for evaluating effectiveness of efforts in the provision of improved services to patients with heart disease, cancer, stroke and related diseases.
P.L. 89-749:
Establish State and areawide health goals.
Define total health needs of all people and communities within area served for meeting health goals.
☐ Inventory and identify relation- ships among varied local, State, na- tional, governmental and voluntary

programs; regional medical programs, mental health, health facilities, manpower, medicare — so that these programs can be assisted in making more effective impact with their resources.

Provide information, analyses, and recommendations which can serve as the basis for the Governor, other health programs and communities to make more effective allocations of resources in meeting health goals.

Provide a focus for interrelating health planning with planning for education, welfare and community development.

☐ Strengthen planning, evaluation, and service capacities of all participants in the health endeavor.

Provide support for the initiation, integration, and development of pilot projects for better delivery of health services; develop plans for targeting flexible formula and project grants at problems and gaps identified by the planning process.

Specific Planning Relationships

There are a variety of ongoing health planning and community health organization activities. Many are supported in part by the Public Health Service, such as Regional Medical Programs (P.L. 89–239),

community mental health centers, areawide health facility planning, and the Hill-Burton programs. These activities are stimulating the creation of new relationships between health resources and functions as well as assisting in the creation of additional resources in the stimulation of more effective performance of functions for the purpose of achieving more effective attainment of identified health goals. Each of these programs requires participation not only by a broad range of health professionals but also by representatives of the consumers of health services. Each of these programs is dependent upon the interaction of the full range of relevant health interests, including those in the public sector and the private voluntary sector in achieving the particular progam goals.

Comprehensive health planning (P.L. 89-749) is designed to provide assistance in the development of more effective relationships among such health programs and to provide a better basis for relating these programs to the accomplishment of overall health objectives at the State and local level. Based on similar principles of broad participation, it calls for the stimulation of all parties to contribute to the goal of insuring the availability of comprehensive health services to all who need them.

Both regional medical programs and comprehensive health planning are intended to strengthen creative Federalism-more productive mechanisms for partnership and cooperation between the national, State and local levels of government, the public and voluntary private health activities, and the academic and health services environments. P.L. 89-749 will create planning resources at the State and local level. The information, analyses, and plans developed by these planning resources can provide invaluable assistance to State and local authorities, to voluntary health organizations and institutions, and to the other health programs involved in planning and developing the organization of health activities which are supported through other Public Health Service grant funds. This planning resource created under Section 314(a) will thus contribute to the more effective accomplishment of health objectives and the setting of priorities in achieving those objectives through the activities supported under the other sections of this Law. In addition, the resource will contribute to the determination of priorities for action not only by those with public responsibility and accountability for health services but also by the many other health organizations, institutions, and

personnel which bear the direct responsibility for the delivery of health services for most of the population. P.L. 89–749 recognizes that the accomplishment of improvements in the quality and coverage in health services, both personal and environmental, depends upon the voluntary participation and energies of both the private and public sectors of the health endeavor.

The planning, operational programs, and organizational frameworks being created under the Regional Medical Programs, community mental health centers, and areawide health facility planning groups, including the advisory groups established for other programs such as the Regional Medical Programs, should serve as sources of strength and valuable assistance for the areawide and State-wide health planning councils created under P.L. 89–749 and for the planning resources created under this Law.

The broad range of health interests represented in Regional Medical Program planning efforts, along with other appropriate health interests, will be essential participants and contributors to the State health planning council and to the activities of the health planning agency. When the activities of that agency address

themselves to the problems of extending high-quality personal health services which fully benefit from the developments in new medical knowledge, the cooperative involvement of these health interests in both the Regional Medical Program planning and development and in the planning and evaluation activities under P.L. 89–749 will make an essential contribution to productive relationship between these activities.

The comprehensive health planning activities will use data available from many sources including that generated or analyzed by the Regional Medical Programs, particularly on health status of populations effected, health resources, and health problems and needs. The comprehensive health planning activities can also benefit from the experience obtained under the Regional Medical Programs which have represented an exploratory effort of considerable importance in developing an environment for concerted planning by many elements of the health endeavor and in the implementation, development and evaluation of new systems for the facilitation of the delivery of the benefits of medical advance in specific disease areas through more effective means of communication, education, training, organization, and delivery of health services. Many of the planning and implementation activities under the Regional Medical Programs will have implications and applications to a broader range of health problems than heart disease, cancer, stroke, and related diseases. The mechanisms created by the Regional Medical Program can be useful in achieving the broad goals of comprehensive health stated under P.L. 89–749.

Training Health Planners

Section 314(c) of P.L. 89–749 authorizes grants to public or nonprofit organizations for "training, studies, and demonstrations," in order to advance the state of health planning art and increase the supply of competent health planners.

For the first years, emphasis will be placed on increasing health planning manpower. (Until now, Public Health Service effort has been limited to ad hoc short courses or inservice training.) This new activity will help meet a critical shortage faced by regional medical programs, medical centers, operating health agencies, as well as comprehensive health planning agencies about to be launched.

Operating Grants

Section 314(d) of P.L. 89-749 authorizes formula grants to State health and mental health authorities for comprehensive public health service. The Act brings together a group of previously compartmented or categorical Public Health Service grants. Grant awards will depend on a plan submitted by the health agency which reflects the way in which the State intends to use the funds as part of an effort to provide adequate Public Health Services. This plan, in turn, must be in accord with the State's comprehensive health planning.

Section 314(e), authorizing project grants for "health services development," broadens and consolidates a series of Public Health Service project grants, making possible Federal support for new and innovative projects, locally determined, to meet health needs of limited geographic scope or specialized regional or national significance; stimulating and initially supporting new programs of health services, and undertaking studies, demonstrations, or training designed to develop new or improved methods of providing health services. The first two of these categories of health service development grant must conform to objectives, priorities, and plans of comprehensive State health planning.

With the exception of the statutory requirement that the programs supported by these grants must conform to comprehensive State health planning, P.L. 89-749 formula and project grants bear the same relation to the comprehensive health planning process as do, for example, the operational grants under regional medical programs, air pollution control, or community mental health center staffing.

The operational grants under P.L. 89-239 will support an interrelated program of activities which utilize regional cooperative arrangements to accomplish the objectives of that law in the fields of heart disease, cancer, stroke, and related diseases. The cooperative arrangements and the specific program elements are viewed by many regions as providing useful models for application to a wide spectrum of health problems which can be implemented through other means and which will have close relevance to the achievement of many of the activities supported under P.L. 89-749 and other health programs. Conversely, the regional medical programs can benefit from the planning and operational activities of other health programs including those supported under P.L. 89–749. Other programs supported by Public Health Service funds such as mental health, migrant health, and air pollution can have the same type of productive interrelationship with the comprehensive health planning programs.

The Public Health Service has a responsibility to prevent waste of scarce resources through useless duplication. To assure the most effective interrelationship among these and other Public Health Service grant programs, the Public Health Service is currently developing informational, and review systems to promote effective coordination between all of its varied grant programs.

EXHIBIT XII

Public Law 89–239 89th Congress, S. 596 October 6, 1965 An Act

Heart Disease, Cancer, and Stroke Amendments of 1965.

To amend the Public Health Service Act to assist in combating heart disease, cancer, stroke, and related diseases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Heart Disease, Cancer, and Stroke Amendments of 1965".

SEC. 2. The Public Health Service Act (42 U.S.C., ch. 6A) is amended by adding at the end thereof the following new title:

"TITLE IX—EDUCATION, RESEARCH, TRAINING, AND DEMONSTRATIONS IN THE FIELDS OF HEART DISEASE, CANCER, STROKE, AND RELATED DISEASES

"Purposes

"Sec. 900. The purposes of this title are—"(a) Through grants, to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases:

"(b) To afford to the medical profession and the medical institutions of the Nation, through such cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases; and

"(c) By these means, to improve generally the health manpower and facilities

available to the Nation, and to accomplish these ends without interfering with the patterns, or the methods of financing, of patient care or professional practice, or with the administration of hospitals, and in cooperation with practicing physicians, medical center officials, hospital administrators, and representatives from appropriate voluntary health agencies.

"Authorization of Appropriations

"SEC. 901. (a) There are authorized to be appropriated \$50,000,000 for the fiscal year ending June 30, 1966, \$90,000,000 for the fiscal year ending June 30, 1967, and \$200,000,000, for the fiscal year ending June 30, 1968, for grants to assist public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private institutions and agencies in planning, in conducting feasibility studies, and in operating pilot projects for the establishment of regional medical programs of research, training, and demonstration activities for carrying out the purposes of this title. Sums appropriated under this section for any fiscal year shall remain available for making such grants until the end of the fiscal year following the fiscal year for which the appropriation is made.

"(b) A grant under this title shall be for part or all of the cost of the planning or other activities with respect to which the application is made, except that any such grant with respect to construction of, or provision of built-in (as determined in accordance with regulations) equipment for, any facility may not exceed 90 per centum of the cost of such construction or equipment.

"(c) Funds appropriated pursuant to this title shall not be available to pay the cost of hospital, medical, or other care of patients except to the extent it is, as determined in accordance with regulations, incident to those research, training, or demonstration activities which are encompassed by the purposes of this title. No patient shall be furnished hospital, medical, or other care at any facility incident to research, training, or demonstration activities carried out with funds appropriated pursuant to this title, unless he has been referred to such facility by a practicing physician.

"Definitions

"SEC. 902. For the purposes of this title—
"(a) The term 'regional medical program'
means a cooperative arrangement among a
group of public or nonprofit private institutions or agencies engaged in research, training, diagnosis, and treatment relating to
heart disease, cancer, or stroke, and, at the
option of the applicant, related disease or
diseases: but only if such group—

- "(1) is situated within a geographic area, composed of any part or parts of any one or more States, which the Surgeon General determines, in accordance with regulations, to be appropriate for carrying out the purposes of this title;
- "(2) consists of one or more medical centers, one or more clinical research centers, and one or more hospitals; and
- "(3) has in effect cooperative arrangements among its component units which the Surgeon General finds will be adequate for effectively carrying out the purposes of this title.
- "(b) The term 'medical center' means a medical school or other medical institution involved in postgraduate medical training and one or more hospitals affiliated therewith for teaching, research, and demonstration purposes.
- "(c) The term 'clinical research center' means an institution (or part of an institution) the primary function of which is research, training of specialists, and demonstrations and which, in connection therewith, provides specialized, high-quality diagnostic and treatment services for inpatients and outpatients.
- "(d) The term 'hospital' means a hospital as defined in section 625(c) or other health facility in which local capability for diagnosis and treatment is supported and augmented by the program established under this title.
- "(e) The term 'nonprofit' as applied to any institution or agency means an institution or agency which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

"(f) The term 'construction' includes alteration, major repair (to the extent permitted by regulations), remodeling and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

"Grants for Planning

"Sec. 903. (a) The Surgeon General, upon the recommendation of the National Advisory Council on Regional Medical Programs established by section 905 (hereafter in this title referred to as the 'Council'), is authorized to make grants to public or non-profit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist them in planning the development of regional medical programs.

- "(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it contains or is supported by—
- "(1) reasonable assurances that Federal funds paid pursuant to any such grant will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder:
- "(2) reasonable assurances that the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;
- "(3) reasonable assurances that the applicant will make such reports, in such form and containing such information as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access theresto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and
- "(4) a satisfactory showing that the applicant has designated an advisory group, to advise the applicant (and the institutions and agencies participating in the resulting regional medical program) in formulating and carrying out the plan

for the establishment and operation of such regional medical program, which advisory group includes practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary health agencies, and representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program and members of the public familiar with the need for the services provided under the program.

"Grants for Establishment and Operation of Regional Medical Programs

"SEC. 904. (a) The Surgeon General, upon the recommendation of the Council, is authorized to make grants to public or nonprofit private universities, medical schools, research institutions, and other public or nonprofit private agencies and institutions to assist in establishment and operation of regional medical programs, including construction and equipment of facilities in connection therewith.

"(b) Grants under this section may be made only upon application therefor approved by the Surgeon General. Any such application may be approved only if it is recommended by the advisory group described in section 903(b)(4) and contains or is supported by reasonable assurances that—

- "(1) Federal funds paid pursuant to any such grant (A) will be used only for the purposes for which paid and in accordance with the applicable provisions of this title and the regulations thereunder, and (B) will not supplant funds that are otherwise available for establishment or operation of the regional medical program with respect to which the grant is made;
- "(2) the applicant will provide for such fiscal control and fund accounting procedures as are required by the Surgeon General to assure proper disbursement of and accounting for such Federal funds;

Records.

"(3) the applicant will make such reports, in such form and containing such information as the Surgeon General may from: time to time reasonably require, and

will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports; and

"(4) any laborer or mechanic employed by any contractor or subcontractor in the performance of work on any construction aided by payments pursuant to any grant under this section will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Davis-Bacon Act, as amended (40 U.S.C. 276a-276a-5); and the Secretary of Labor shall have, with respect to the labor standards specified in this paragraph, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 5 U.S.C. 133z-15) and section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c).

"National Advisory Council on Regional Medical Programs

Appointment of members.

"SEC. 905. (a) The Surgeon General, with the approval of the Secretary, may appoint, without regard to the civil service laws, a National Advisory Council on Regional Medical Programs. The Council shall consist of the Surgeon General, who shall be the chairman, and twelve members, not otherwise in the regular full-time employ of the United States, who are leaders in the fields of the fundamental sciences, the medical sciences, or public affairs. At least two of the appointed members shall be practicing physicians, one shall be outstanding in the study, diagnosis, or treatment of heart disease, one shall be outstanding in the study, diagnosis, or treatment of cancer, and one shall be outstanding in the study, diagnosis, or treatment of stroke.

Term of office.

"(b) Each appointed member of the Council shall hold office for a term of four years, except that any member appointed to fill a vacancy prior to the expiration of the term

for which his predecessor was appointed shall be appointed for the remainder of such term, and except that the terms of office of the members first taking office shall expire, as designated by the Surgeon General at the time of appointment, four at the end of the first year, four at the end of the second year, and four at the end of the third year after the date of appointment. An appointed member shall not be eligible to serve continuously for more than two terms.

Compensation.

"(c) Appointed members of the Council, while attending meetings or conferences thereof or otherwise serving on business of the Council, shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding \$100 per day, including traveltime, and while so serving away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b-2) for persons in the Government service employed intermittently.

Applications for grants, recommendations.

"(d) The Council shall advise and assist the Surgeon General in the preparation of regulations for, and as to policy matters arising with respect to, the administration of this title. The Council shall consider all applications for grants under this title and shall make recommendations to the Surgeon General with respect to approval of applications for and the amounts of grants under this title.

"Regulations"

"Sec. 906. The Surgeon General, after consultation with the Council, shall prescribe general regulations coverng the terms and conditions for approving applications for grants under this title and the coordination of programs assisted under this title with programs for training, research, and demonstrations relating to the same diseases assisted or authorized under other titles of this Act or other Acts of Congress.

"Information on Special Treatment and Training Centers

"SEC. 907. The Surgeon General shall establish, and maintain on a current basis, a list or lists of facilities in the United States equipped and staffed to provide the most advanced methods and techniques in the diagnosis and treatment of heart disease, cancer, or stroke, together with such related information, including the availability of advanced specialty training in such facilities, as he deems useful, and shall make such list or lists and related information readily available to licensed practitioners and other persons requiring such information. To the end of making such list or lists and other information most useful, the Surgeon General shall from time to time consult with interested national professional organizations.

Report to President and Congress

"Sec. 908. On or before June 30, 1967, the Surgeon General after consultation with the Council, shall submit to the Secretary for transmission to the President and then to the Congress, a report of the activities under this title together with (1) a statement of the relationship between Federal financing and financing from other sources of the activities undertaken pursuant to this title, (2) an appraisal of the activities assisted under this title in the light of their effectiveness in carrying out the purposes of this title, and (3) recommendations with respect to extension or modification of this title in the light thereof.

"Records and Audit

"Sec. 909. (a) Each recipient of a grant under this title shall keep such records as the Surgeon General may prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is made or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such records as will facilitate an effective audit.

"(b) The Secretary of Health, Education, and Welfare and the Comptroller General of

the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of any grant under this title which are pertinent to any such grant."

SEC. 3. (a) Section 1 of the Public Health Service Act is amended to read as follows:

"SECTION 1. Titles I to IX, inclusive, of this Act may be cited as the 'Public Health Service Act'."

(b) The Act of July 1, 1944 (58 Stat. 682), as amended, is further amended by renumbering title IX (as in effect prior to the enactment of this Act) as title X, and by renumbering sections 901 through 914 (as in effect prior to the enactment of this Act), and references thereto, as sections 1001 through 1014, respectively.

APPROVED OCTOBER 6, 1965, 10:15 A.M.

Legislative History:

House Report No. 963 accompanying H.R. 3140 (Comm. on Interstate and Foreign Commerce).

Senate Report No. 368 (Comm. on Labor and Public Welfare).

Congressional Record, Vol. 111 (1965):

June 25: Considered in Senate.

June 28: Considered and passed Senate.

Sept. 23: H.R. 3140 considered in House. Sept. 24: Considered and passed House,

amended, in lieu of H.R. 3140.

Sept. 29: Senate concurred in House amendments.

EXHIBIT XIII

Regulations

Regional Medical Programs

March 18, 1967

SUBPART E—GRANTS FOR REGIONAL MEDICAL PROGRAMS

(Added 1/18/67, 32 FR 571.)

AUTHORITY: The provisions of this Subpart E issued under sec. 215, 58 Stat. 690, sec. 906, 79 Stat. 930; 42 U.S.C. 216, 299f, Interpret or apply secs. 900, 901, 902, 903, 904, 905, 909, 79 Stat. 926, 927, 928, 929, 300, 42 U.S.C. 299, 299a, 299b, 299c, 299d. 299e, 299i.

☐ 54.401 APPLICABILITY.

The provisions of this subpart apply to grants for planning, establishment, and operation of regional medical programs as authorized by Title IX of the Public Health Service Act, as amended by Public Law 89-239.

☐ 54.402 DEFINITIONS.

- (a) All terms not defined herein shall have the meaning given them in the Act.
- (b) "Act" means the Public Health Service Act, as amended.
- (c) "Title IX" means Title IX of the Public Health Service Act as amended.
- (d) "Related diseases" means those diseases which can reasonably be considered to bear a direct relationship to heart disease, cancer, or stroke.
- (e) "Title IX diseases" means heart disease, cancer, stroke, and related diseases.
- (f) "Program" means the regional medical program as defined in section 902(a) of the Act.
- (g) "Practicing physician" means any physician licensed to practice medicine in

accordance with applicable State laws and currently engaged in the diagnosis or treatment of patients.

- (h) "Major repair" includes restoration of an existing building to a sound state.
- (i) "Built-in equipment" is equipment affixed to the facility and customarily included in the construction contract.
- (j) "Advisory group" means the group designated pursuant to section 903(b)(4) of the Act.
- (k) "Geographic area" means any area that the Surgeon General determines forms an economic and socially related region, taking into consideration such factors as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; presence and distribution of educational, medical and health facilities and programs, and other activities which in the opinion of the Surgeon General are appropriate for carrying out the purposes of Title IX.

□ 54.403 ELIGIBILITY.

In order to be eligible for a grant, the applicant shall:

- (a) Meet the requirements of section 903 or 904 of the Act:
 - (b) Be located in a State:
- (c) Be situated within a geographic area appropriate under the provisions of this subpart for carrying out the purposes of the Act.

☐ 54.404 APPLICATION.

- (a) Forms. An application for a grant shall be submitted on such forms and in such manner as the Surgeon General may prescribe.
- (b) Execution. The application shall be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant all of the obligations specified in the terms and conditions of the grant including those contained in these regulations.
- (c) Description of program. In addition to any other pertinent information that the Surgeon General may require, the applicant shall submit a description of the program in sufficient detail to clearly identify the nature, need, purpose, plan, and methods of the program, the nature and functions of the participating institutions, the geographic

area to be served, the cooperative arrangements in effect, or intended to be made effective, within the group, the justification supported by a budget or other data, for the amount of the funds requested, and financial or other data demonstrating that grant funds will not supplant funds otherwise available for establishment or operation of the regional medical program.

- (d) Advisory group; establishment; cvt-dence. An application for a grant under section 903 of the Act shall contain or be supported by documentary evidence of the establishment of an advisory group to provide advice in formulating and carrying out the establishment and operation of a program.
- (e) Advisory group; membership; description. The application or supporting material shall describe the selection and membership of the designated advisory group, showing the extent of inclusion in such group of practicing physicians, members of other health professions, medical center officials, hospital administrators, representatives from appropriate medical societies, voluntary agencies, representatives of other organizations, institutions and agencies concerned with activities of the kind to be carried on under the program, and members of the public familiar with the need for the services provided under the program.
- (f) Construction; purposes, plans, and specifications; narrative description. With respect to an application for funds to be used in whole or part for construction as defined in Title IX, the applicant shall furnish in sufficient detail plans and specifications as well as a narrative description, to indicate the need, nature, and purpose of the proposed construction.
- (g) Advisory group; recommendation. An application for a grant under section 904 of the Act shall contain or be supported by a copy of the written recommendation of the advisory group.

☐ 54.405 TERMS, CONDITIONS, AND ASSURANCES.

In addition to any other terms, conditions, and assurances required by law or imposed by the Surgeon General, each grant shall be subject to the following terms, conditions, and assurances to be furnished by the grantee. The Surgeon General may at any time approve exceptions where he finds that

such exceptions are not inconsistent with the Act and the purposes of the program.

- (a) Use of funds. The grantee will use grant funds solely for the purposes for which the grant was made, as set forth in the approved application and award statement. In the event any part of the amount paid a grantee is found by the Surgeon General to have been expended for purposes or by any methods contrary to the Act, the regulations of this subpart, or contrary to any condition to the award, then such grantee, upon being notified of such finding, and in addition to any other requirement, shall pay an equal amount to the United States. Changes in grant purposes may be made only in accordance with procedures established by the Surgeon General.
- (b) Obligation of funds. No funds may be charged against the grant for services performed or material or equipment delivered, pursuant to a contract or agreement entered into by the applicant prior to the effective date of the grant.
- (c) Inventions or discoveries. Any grant award hereunder in whole or in part for research is subject to the regulations of the Department of Health, Education, and Welfare as set forth in Parts 6 and 8 of Title 45, as amended. Such regulations shall apply to any program activity for which grant funds are in fact used whether within the scope of the program as approved or otherwise. Appropriate measures shall be taken by the grantee and by the Surgeon General to assure that no contracts, assignments, or other arrangements inconsistent with the grant obligation are continued or entered into and that all personnel involved in the supported activity are aware of and comply with such obligation. Laboratory notes, related technical data, and information pertaining to inventions or discoveries made through activities supported by grant funds shall be maintained for such periods, and filed with or otherwise made available to the Surgeon General or those he may designate at such times and in such manner as he may determine necessary to carry out such Department regulations.
- (d) Reports. The grantee shall maintain and file with the Surgeon General such progress, fiscal, and other reports, including reports of meetings of the advisory group convened before and after award of a grant

under section 904 of the Act, as the Surgeon General may prescribe.

- (e) Records retention. All construction, financial, and other records relating to the use of grant funds shall be retained until the grantee has received written notice that the records have been audited unless a different period is permitted or required in writing by the Surgeon General.
- (f) Responsible official. The official designated in the application as responsible for the coordination of the program shall continue to be responsible for the duration of the period for which grant funds are made available. The grantee shall notify the Surgeon General immediately if such official becomes unavailable to discharge this responsibility. The Surgeon General may terminate the grant whenever such official shall become thus unavailable unless the grantee replaces such official with another official found by the Surgeon General to be qualified.

☐ 54.406 AWARD.

Upon recommendation of the National Advisory Council on Regional Medical Programs, and within the limits of available funds, the Surgeon General shall award a grant to those applicants whose approved programs will in his judgment best promote the purposes of Tile IX. In awarding grants, the Surgeon General shall take into consideration, among other relevant factors the following:

- (a) Generally, the extent to which the proposed program will carry out, through regional cooperation, the purposes of Title IX, within a geographic area.
- (b) The capacity of the institutions or agencies within the program, individually and collectively, for research, training, and demonstration activities with respect to Title IX.
- (c) The extent to which the applicant or the participants in the program plan to coordinate or have coordinated the regional medical program with other activities supported pursuant to the authority contained in the Public Health Service Act and other Acts of Congress including those relating to planning and use of facilities, personnel, and equipment, and training of manpower.
- (d) The population to be served by the regional medical program and relationships

- to adjacent or other regional medical programs.
- (e) The extent to which all the health resources of the region have been taken into consideration in the planning and/or establishment of the program.
- (f) The extent to which the participating institutions will utilize existing resources and will continue to seek additional nonfederal resources for carrying out the objectives of the regional medical program.
- (g) The geographic distribution of grants throughout the Nation.

☐ 54.407 TERMINATION.

- (a) Termination by the Surgeon General. Any grant award may be revoked or terminated by the Surgeon General in whole or in part at any time whenever he finds that in his judgment the grantee has failed in a material respect to comply with requirements of Title IX and the regulations of this subpart. The grantee shall be promptly notified of such finding in writing and given the reasons therefor.
- (b) Termination by the grantee. A grantee may at any time terminate or cancel its conduct of an approved project by notifying the Surgeon General in writing setting forth the reasons for such termination.
- (c) Accounting. Upon any termination, the grantee shall account for all expenditures and obligations charged to grant funds: Provided, That to the extent the termination is due in the judgment of the Surgeon General to no fault of the grantee, credit shall be allowed for the amount required to settle nt costs demonstrated by evidence satisfactory to the Surgeon General to be minimum settlement costs, any noncancellable obligations incurred prior to receipt of notice of termination.

☐ 54.408 NONDISCRIMINATION.

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. Regulations implementing the statute have been issued as Part 80 of the Title 45, Code of Federal Regulations. The regional medical programs pro-

vide Federal financial assistance subject to the Civil Rights Act and the regulations. Each grant is subject to the condition that the grantee shall comply with the requirements of Executive Order 11246, 30 F.R. 12319, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

☐ 54.409 EXPENDITURES BY GRANTEE,

- (a) Allocation of costs. The grantee shall allocate expenditures as between direct and indirect costs in accordance with generally accepted and established accounting practices or as otherwise prescribed by the Surgeon General.
- (b) Direct costs in general. Funds granted for direct costs may be expended by the grantee for personal services, rental of space, materials, and supplies, and other items of necessary cost as are required to carry out the purposes of the grant. The Surgeon General may issue rules, instructions, interpretations, or limitations supplementing the regulations of this subpart and prescribing the extent to which particular types of expenditures may be charged to grant funds.
- (c) Direct costs; personal scrvices. The costs of personal services are payable from grant funds substantially in proportion to the time or effort the individual devotes to carrying out the purpose of the grant. In such proportion, such costs may include all direct costs incident to such services, such as salary during vacations and retirement and workmen's compensation charges, in accordance with the policies and accounting practices consistently applied by the grantee to all its activities.
- (d) Direct costs; care of patients. The cost of hospital, medical or other care of patients is payable from grant funds only to the extent that such care is incident to the research, training, or demonstration activities supported by a grant hereunder. Such care shall be incident to such activities only if reasonably associated with and required for the effective conduct of such activities, and no such care shall be charged to such funds unless the referral of the patient is documented with respect to the name of the practicing physician making the referral, the name of the patient, the date of referral, and any other relevant information which

may be prescribed by the Surgeon General. Grant funds shall not be charged with the cost of—

- (1) Care for intercurrent conditions (except of an emergency nature where the intercurrent condition results from the care for which the patient was admitted for treatment) that unduly interrupt, postpone, or terminate the conduct of such activities.
- (2) Inpatient care if other care which would equally effectively further the purposes of the grant, could be provided at a smaller cost.
- (3) Bed and board for inpatients in excess of the cost of semiprivate accommodations unless required for the effective conduct of such activities. For the purpose of this paragraph, "semiprivate accommodations" means two-bed, three-bed, and four-bed accommodations.

☐ 54.410 PAYMENTS.

The Surgeon General shall, from time to time, make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement for expenses to be incurred or incurred to the extent he determines such payments necessary to carry out the purposes of the grant.

☐ 54.411 DIFFERENT USE OR TRANSFER: GOOD CAUSE FOR OTHER USE.

(a) Compliance by grantees. If, at any time, the Surgeon General determines that the eligibility requirements for a program are no longer met, or that any facility or equipment the construction or procurement of which was charged to grant funds is, during its useful life, no longer being used for the purposes for which it was constructed or procured either by the grantee or any transferee, the Government shall have the right to recover its proportionate share of the value of the facility or equipment from either the grantee or the transferee or any institution that is using the facility or equipment. The Government's proportionate share shall be the amount bearing the same ratio to the then value of the facility or equipment, as determined by the Surgeon General, as the amount the Federal participation bore to the cost of construction or procurement.

- (b) Different use or transfer; notification. The grantee shall promptly notify the Surgeon General in writing if at any time during its useful life the facility or equipment for construction or procurement of which grant funds were charged is no longer to be used for the purposes for which it was constructed or procured or is sold or otherwise transferred.
- (c) Forgiveness. The Surgeon General may for good cause release the grantee or other owner from the requirement of continued eligibility or from the obligation of continued use of the facility or equipment for the grant purposes. In determining whether good cause exists, the Surgeon General shall take into consideration, among other factors, the extent to which—
- (1) The facility or equipment will be devoted to research, training, demonstrations, or other activities related to Title IX diseases.
- (2) The circumstances calling for a change in the use of the facility were not known, or with reasonable diligence could not have been known to the applicant, at the time of the application, and are circumstances reasonably beyond the control of the applicant or other owner.
- (3) There are reasonable assurances that other facilities not previously utilized for Title IX purposes will be so utilized and are substantially the equivalent in nature and extent for such purposes.

☐ 54.412 PUBLICATIONS.

Grantees may publish materials relating to their regional medical program without prior review provided that such publications carry a footnote acknowledging assistance from the Public Health Service, and indicating that findings and conclusions do not represent the views of the Service.

☐ 54.413 COPYRIGHTS.

Where the grant-supported activity results in copyrightable material, the author is fro to copyright, but the Public Health Servireserves a royalty-free, nonexclusive, irreveable license for use of such material.

☐ 54.414 INTEREST.

Interest or other income earned on payments under this subpart shall be paid to the United States as such interest is received by the grantee.

EXHIBIT XIV

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